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Food and Drug Administration
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Docket No. 02N-0278 – Comments On Paperwork Reduction Act/Collection of Information – Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The National Coalition of Food Importing Associations (NCFIA) is pleased to submit comments to the Office of Management and Budget (OMB) and the Food and Drug Administration (FDA) on the FDA's notice of proposed rulemaking, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5428 (Feb. 3, 2003) (hereinafter Prior Notice Proposed Rule).

NCFIA is a coalition of trade associations that represent different segments of the food importing community. Members of NCFIA include the following associations: American Spice Trade Association, Cheese Importers Association of America, Association of Food Industries, The Cocoa Merchants' Association of America, and the National Fisheries Institute (NFI). If implemented as proposed, the information collection burdens the Prior Notice Rule imposes would dramatically affect NCFIA members.

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FDA invited comments on the following aspects of Prior Notice Proposed Rule and the Paperwork Reduction Act of 1995 (PRA):

1. Whether the proposed collection of information is necessary for the functions of FDA, including whether the information has practical utility;

2. Whether FDA's estimate of the burden of the proposed collection of information is accurate;

3. Whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and

4. Whether there are ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques and other information technologies.

The comments of NCFIA follow below.

1. The proposed collection of information is not necessary for the proper performance of FDA functions and the information does not have practical utility.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) imposes a new, but limited, requirement upon those who import food into the United States. Section 307 of the Bioterrorism Act (21 U.S.C. § 381(m)) states that FDA, after consultation with the U.S. Customs Service (Customs), shall, require identification of the following prior to importation:

- The article;
- The manufacturer;
- The shipper;
- If known within the time the notice is required to be provided, the grower(s) of the article;
- The country from which the article originates;
- The country from which the article is shipped; and
- The anticipated port of entry.

Information collection, then, is at the core of the Prior Notice Proposed Rule. The purpose that underlies importers submitting this information and FDA collecting the information is set forth in the Bioterrorism Act: "[to enable] such article to be inspected at ports of entry into the United States." § 307 of the Bioterrorism Act, 21 U.S.C. § 381(m)(1).

From the seven, straightforward pieces of information the Bioterrorism Act requires be provided, FDA constructs a prior notice submission form that is potentially 5 pages long, with hundreds of separate data elements. 68 Fed. Reg. at 5464. In the Prior Notice Proposed Rule, FDA goes far beyond what the Bioterrorism Act requires and far exceeds what is necessary to enable FDA to identify which articles of food offered for import it should inspect.

FDA proposes that the prior notice to be submitted would have to contain information that identifies:

- The individual and firm submitting the prior notice, including:
    - Name
    - Address
    - Phone number
    - Fax number
    - E-mail address
    - FDA registration number
- The entry type and Automated Commercial System (ACS) entry number or other Customs identification number associated with the import;
- If the article of food is already under hold for failure to provide adequate prior notice, the location where the article is being held;
- The identity of the article of food being imported or offered for import, including:
    - The complete FDA product code;
    - The common or usual name or market name;
    - The trade or brand name, if different from the common or usual name;
    - The quantity described from smallest package size to largest container; and
    - The lot or code numbers or other identifier of the food if applicable.
- The manufacturer, including:
    - Name
    - Address
    - Phone number

  - Fax number
  - E-mail address
  - FDA registration number

- All known growers, including;

  - Name
  - Address
  - Phone number
  - Fax number
  - E-mail address
  - FDA registration number

- The country from which the article originates

- The shipper

  - Name
  - Address
  - Phone number
  - Fax number
  - E-mail address
  - FDA registration number

- The country from which the article of food was shipped

- The anticipated arrival information, including port, date, and time

- The importer, including:

  - Name
  - Address
  - Phone number
  - Fax number
  - E-mail address
  - FDA registration number

- The owner, including:

  - Name
  - Address

- Phone number
- Fax number
- E-mail address
- FDA registration number

- The consignee, including:
  - Name
  - Address
  - Phone number
  - Fax number
  - E-mail address
  - FDA registration number

- All carriers, including:
  - Name
  - Address
  - Phone number
  - Fax number
  - E-mail address
  - FDA registration number

Thus, FDA is seeking far more information than the seven simple data elements set forth in Section 307 of the Bioterrorism Act. Many of the new information elements currently are not normally provided to the importer who will be making the prior notice. For instance, the importer usually does not know a product's brand or trade name, and lot numbers. Package sizes often are not provided under current practice. In addition, depending upon the mode of transportation, the importer does not normally know most of the precise arrival information that would be required by proposed 21 C.F.R. § 1.288(k) (68 Fed. Reg. at 5462). An importer does not usually know with any degree of accuracy the time of day ocean freight will arrive into the United States port – section 307, incidentally, requires only identification of the port of entry and does not mandate the detail of the Prior Notice Proposed Rule. Moreover, it is likely that when Congress used the term "port of entry" in the statute, it was referencing the existing and well-understood term within 19 C.F.R. § 101.1 and not this convoluted requirement now proposed. The Bioterrorism Act does not require this kind of detailed information and it may be difficult to obtain.

As another example, the Prior Notice Proposed Rule requires the importer to provide the ACS number in the prior notice. However, the broker, not the importer, generates the number and it is not publicly available. The importer and the broker may be, but are not necessarily, the same entity and there is no mechanism for communicating this information from the broker who generates

the number to the importer filing the prior notice. The Bioterrorism Act does not require this information, yet FDA is requiring it.

Additionally, in many instances, the prior notice will have to be filed before the broker, under Customs regulations, can make the ACS entry. Thus, the broker will have to generate, save, but not submit the ACS entry, then will than have to go back into its system a second time when Customs regulations allow the broker to file the ACS information. What was once a single coordinated action (file FDA/OASIS documentation and ACS entry at same time) now has become a three-step process.

The Prior Notice Proposed Rule also enormously increases the paperwork burden by requiring separate notices for every article from a different manufacturer or grower. 68 Fed. Reg. at 5435, col. 2. Such a requirement would result in many more prior notice filings without in any way aiding FDA's ability to identify imports to be inspected. For example, in the case of commingled products, the product may come from dozens or even hundreds of known and unknown growers/sources. Because the product is commingled in a single vat, drum, tanker, rail car, or other bulk holding device, identifying each grower or manufacturer in a separate notice will not allow FDA to segregate out specific articles to inspect.

FDA deviates far from the requirements of Section 307, 21 U.S.C. § 381(m), without ever explaining how demanding so many details will effectuate the purpose of the Bioterrorism Act. Specifically, there is no explanation as to why this information will allow FDA to determine which imports to inspect. FDA states only that it wishes to have this information but does not explain except in the most conclusory of terms, how this information will allow it to perform the functions Congress assigned to the agency under the Bioterrorism Act.

FDA essentially shifts the burden of explanation and refutation to the information submitters. The statute does not require this information; it is FDA, not affected industry, who should be required to put forth an explanation for needing so much information.

2. FDA's estimates of the burdens and costs of the proposed collection of information are wildly understated.

FDA recognizes that this rule will require fundamental changes in how the business of the importation of food is conducted. Yet, in making this recognition, FDA fails to consider the costs to the many entities that will find their importing businesses radically altered.

Under the Prior Notice Proposed Rule, reams of information that have never been collected before will now have to be supplied. Importers, brokers, customers, suppliers, manufacturers, shippers, warehouses, and others will all have different pieces of information that will have to be communicated for the first time, or will have to be communicated in a different way, or at a different time. Because providing this information will be essential to complying with the prior notice

requirements, contracts amongst these entities may have to be renegotiated. In addition, customary business forms and documents will have to be altered. FDA makes no estimate at all of these costs.

Other of FDA's assumptions regarding the information collection costs of the Prior Notice Proposed Rule are plainly flawed. FDA assumes only 77,427 filers will need to be educated about the Prior Notice Proposed Rule. 68 Fed. Reg. at 5458, col. 1. The number is much greater for the following reasons, among others:

- FDA assumes only one employee and a supervisor will need to be trained in the new system. It is customary for an importer, depending upon its size, to have at least two trained filers – this is the standard business practice for accomplishing ACS/OASIS filings currently. At least two filers, and likely many more, including possibly, an importer or broker's entire filing staff and supervisors will need to understand the prior notice filing system.

- Firms will need to educate their suppliers, manufacturers, customers, drivers, suppliers, warehouses, growers, carriers, shippers, and other entities involved the importation of food. As these entities control much of the information the Prior Notice Proposed Rule requires be disclosed, they will need to learn the rule's requirements, even if they have no filing responsibilities.

FDA also assumes that there are 4.7 million line entries per year and that each line will require a separate notice. 68 Fed. Reg. at 5435, col. 2 and 5442, col. 2 . Yet, FDA calculates that there will be only 1.8 million notices filed per year. 68 Fed. Reg. at 5458, col. 2. FDA understates the number of notices to be filed by almost 3 million.

As an example, NFI is informed that import entries currently combine a variety of similar goods (e.g., different sizes of shrimp) into one line entry. The Prior Notice Proposed Rule would require that each size of shrimp be broken out into separate notifications. The effect is to dramatically multiple the number of entries and prior notices to be made.

The PRA analysis further assumes one hour to learn the rule if the responsible party has Internet access. 68 Fed. Reg. at 5458, col. 2. If the experience of those supporting this comment is any guide, FDA has grossly underestimated the complexity of its proposal. Attorneys who are well-versed in food law and experienced importers and brokers have spent many, many hours reading the Prior Notice Proposed Rule and trying to understand it.

Moreover, the PRA analysis assumes only 45 minutes of time for a filer to complete the prior notice screens of information. 68 Fed. Reg. at 5458, col. 2. However, the information required in the Prior Notice Proposed Rule does not reside in a single place at this time. The importer or other filer will have to gather the required information from several entities (broker, customer, shipper,

carrier, freight forwarder, manufacturer, supplier, and others). The 45 minutes the PRA allots for filing assumes that all the information is in the control of the importer or other filer. This is certainly not the case; it will require a significant amount of time to compile the required information, check the information, and obtain missing information. In addition, all entries will need to be subjected to intensive proofreading to assure accuracy of data entry. We estimate the time required for filing to be at least 2 hours per notice.

The Prior Notice Proposed Rule requires that filers include the estimated day and time of arrival. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives 3 hours later or 1 hour earlier than reported in the notice, the Prior Notice Proposed Rule requires that the filer correct the arrival information. Proposed 21 C.F.R. § 1.288(k)(2), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives outside this 4-hour arrival window, the prior notice is inadequate, the product will be refused, and a new prior notice must be made. Thus, brokers and importers will need to establish operations that operate around-the-clock, 24 hours a day, seven days a week, to assure that if estimated times of arrival suddenly change, the prior notice can be amended. The PRA does not estimate the costs for an importer, currently operating with normal business hours, to establish a 24/7 filing operation.

NFI, a member of NCFIA, is told that many brokers will need to consider hiring additional staff to provide this service. NCFIA and NFI understand that brokers are estimating that the cost of each import entry will increase by 60-70% if the Prior Notice Rule is implemented as proposed. As the average cost of an entry is approximately $110 currently, this means the additional increase in annual customs brokerage charges that importers (and ultimately, consumers) must bear will exceed $300,000,000 (4.7 million entries X ($110.00 X .6) = $310,200,000). FDA does not consider any of these costs in its PRA analysis.

3. There are ways to enhance the quality, utility, and clarity of the information to be collected.

The Prior Notice Proposed Rule permits filers to amend previously filed notices only under very limited circumstances. The filer may only amend a previously filed notice to add information not known about a product's identity at the time the notice was first made. Proposed 21 C.F.R. § 1.290(a), 68 Fed. Reg. at 5462, col. 2. The filer must also update the notice if arrival dates and time change. Proposed 21 C.F.R. § 1.294, 68 Fed. Reg. at 5462, col. 3. If any of this information is incomplete or inaccurate, the article of food may not enter the United States. Consequently, the accuracy of the many data elements in the notice is crucial. If there is an error in the prior notice, it cannot be corrected; the filer must submit a new one.

Such limited ability to amend will create other enormous paperwork burdens for filers if they are not permitted even to correct minor errors and update changes in information. For instance, the Prior Notice Proposed Rule requires entry of numerous multi-digit alpha and numeric codes. Some

of these same codes are used in the ACS/OASIS system currently. Others will be new, such as establishment registration numbers. Simple errors in the entry of this information are not uncommon now. The Prior Notice Proposed Rule would require entry of even more coded information, with even more opportunity for simple, good faith errors and changes. Yet, there is no provision in the Prior Notice Proposed Rule to allow for error correction. The importer must cancel the old notice and file a new one. Even if an error is discovered, after filing, no corrections may be made.

Moreover, the prior notice system FDA proposes provides no verification that the notice is complete or accurate. The importer has no way to verify information such as FDA establishment registration numbers. Consequently, errors and inadequacies will not come to light until the product arrives at the port. This will result in the product being refused entry and the filing of a new notice, plus attendant costs to the store the product. In the case of perishable product, this may mean the market value of the product is destroyed.

The Prior Notice Proposed Rule could be substantially improved to enhance the quality and clarity of the information collected if FDA adopted a more reasonable approach with regard to amendments and updates to prior notices. In this way, simple errors could be corrected and other changes made without undermining FDA's ability to identify articles to be inspected.

NFI is concerned that additional economic impact and injury will result from the loss or de-valuation of fresh and frozen fish and seafood if FDA improperly or erroneously considers a prior notice to be deficient and bars the product from entering the United States. The short comment time has not allowed NFI to compute these potential losses nor examine in detail FDA's offered analysis.

4. There are ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques and other information technologies.

A very disturbing ramification of the Prior Notice Proposed Rule is the lack of coordination with existing Customs requirements, and indeed with FDA's own existing OASIS requirements. Customs and FDA already collect much of the information covered in the Prior Notice Proposed Rule, albeit usually at a later date. The Prior Notice Proposed Rule establishes a whole, new reporting system that exists on top of the Customs and FDA entry information already required. There is an enormous duplication, with no answer given other than that at some point in the future, FDA hopes to better coordinate with Customs. This lack of coordination and burdensome duplication will significantly increase the cost to import food into the United States. FDA should give greater consideration to coordinating the prior notice requirements with Customs' existing notification and reporting requirements.

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We thank OMB for the opportunity to comment on the PRA portions of FDA's Prior Notice Proposed Rule. As the time to submit comments on what is, most fundamentally, a massive, burdensome information collection-based rule has been extremely limited, we ask that OMB accept further comments at a later date.

Sincerely,

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